REMARKS

Claims 1-55 are pending in the application. The Patent Office acknowledges Applicant's election of Group I, Claims 1-34 and the species election. Therefore, Claims 28, 29, 31 and 32 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-27, 30, 33 and 34 are rejected. Apparently, Claims 35-55 are still pending but should be withdrawn as being drawn to a non-elected invention. Claims 2, 4, 6, 7, 8, 14, 18, 22, 34, 39, 43, 44, 49, 53 and 54 are amended herein. The amendments of the claims, the objections and the various rejections raised in the Office Action are discussed in more detail below.

The Amendments of the Claims

Claims 2, 8, 18 and 34 are amended for clarity. Claims 4, 7, 14, 22, 39, 43, 44, 49, 53 and 54 are amended to correct obvious typographical errors. Claim 6 is amended to correct an obvious punctuation error. The scope of the claims remain unchanged. No new matter is added by virtue of these amendments.

Drawings

A Replacement Sheet of Figure 7B in compliance with 37 CFR 1.121(d) is enclosed, in which the X- and Y-axis are labeled "RFU" and "Time", respectively.

Claim Objections

Claim 4 is objected to because the recitation of "reside" is misspelled. In the amendments submitted herein, "reside" is replaced with "residue" in accordance with the Patent Office's suggestion.

Claims 5 and 6 are objected to because, according to the Patent Office, the recitation of "TK", "AGC", CAMK", "CMGC", "STE", "TKL", "CKI", "Src", "Lyn", "Fyn", "Akt", "MAP" and "MAPKAP2" should be in parenthesis and follow the phrase it abbreviates when used for the first time. Applicant respectfully asserts that the terms recited in Claims 5 and 6 are art recognized and therefore are well known and understood by the skilled artisan. To support Applicant's position, enclosed herein as Exhibit A, is an excerpt of a supplementary table by Manning *et al.*, 2002, "The protein kinase complement of the human genome," Science 298(5600):1912-34, which lists various protein kinases using the terminology used in Claims 5 and 6.

Applicant respectfully requests the objections of Claims 4, 5 and 6 be withdrawn.

Rejection Under 35 U.S.C. § 112, ¶ 2

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, ¶ 2 as allegedly being indefinite. The Patent Office contends that the terms "enzyme recognition moiety" and "other" recited in Claims 1 and 5, respectively, are unclear.

Support for "enzyme recognition moiety" is found throughout the specification, for example, at ¶¶ 29-31.

Applicant respectfully asserts that the term "other" recited in Claim 5 is an art recognized term that refers to certain types of protein kinases. To support Applicant's position, enclosed herein as Exhibit A is an excerpt of a supplementary table by Manning *et al.*, 2002, "The protein kinase complement of the human genome." Science 298(5600):1912-34, in which "Other" is identified as a specific group of protein kinases.

Rejection Under 35 U.S.C. § 112, ¶ 1, Written Description

Claims 1-27, 30, 33 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Patent Office alleges that:

> the specification does not provide a disclosure of any particular structure to function/activity relationship of the claimed substrate compound comprising any hydrophobic moiety capable of integrating the compound into a micelle, any fluorescent moiety, and any enzyme recognition moiety.

Office Action, p. 6. The Patent Office further states that "the specification fails to describe any identification of structural characteristics or properties of any hydrophobic moiety, any fluorescent moiety, any recognition moiety, and any protein kinase." *Id.* The specification also does not disclose a sufficient number of "representatives of any substrate compound comprising any hydrophobic moiety capable of integrating the compound into a micelle, any fluorescent moiety, and any enzyme recognition moiety[.]" *Id.* Applicant traverses the rejection.

The standard for determining compliance with the written description requirement is set forth in M.P.E.P. § 2163.01:

> Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

> [A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

Claim 1, the sole independent claim rejected for alleged lack of written description, is drawn to a substrate compound comprising: a hydrophobic moiety capable of integrating the compound into a micelle, a fluorescent moiety and an enzyme recognition moiety. Written description for each of the elements of Claim 1 is found throughout the specification.

For example, support for "a hydrophobic moiety capable of integrating the substrate compound into a micelle can be found at ¶¶ 21, 68-71 and 124. Examples of hydrophobic moieties can be found at ¶ 72 (C6-C26 *n*-alkyl chains); Scheme 1, ¶ 137 and Scheme 2, ¶ 143 (a C-16 fatty acid acyl group (palmitoyl)); Scheme 3, ¶ 151 and Table 2 (dodecanoyl, tetradecanoyl, nonanoyl groups); Scheme 4, ¶ 153 (a hydrophobic moiety substituted by at least one halogen atom, *e.g.*, *n*-(1H, 1H, 2H, 2H perfluorodecyl-1-thiol-2-acetyl)); Scheme 5, ¶ 156 (N-perfluoro-octanoyl); Scheme 6, ¶ 159 (an octadecanoyl group); Table 3 provides additional examples of hydrophobic moieties (C13, C15 and C17); and Scheme 7, ¶ 165 (a hexadecanoyl group).

Support for "fluorescent moiety" can be found at ¶¶ 11 and 73-90. Examples of fluorescent moieties can be found at ¶ 11 (sulfofluorescein and rhodamine); ¶¶ 75-80 (xanthine substituted ring); ¶¶ 81-82 (rhodamine-type substituted ring); ¶¶ 83-84 (substituted or unsubstituted fluorescein-type ring); ¶ 85 (orthocarboxyrhodamines); ¶ 86 (4,7-dichlororhodamines, rhodamine B, 5-carboxyrhodamine, rhodamine X (ROX), 4,7-dichlororhodamine X (dROX), rhodamine 6G (R6G), 4,7-dichlororhodamine 6G, rhodamine 110 (R110), 4,7-dichlororhodamine 110 (dR110), tetramethylrhodamine (TAMRA) and 4,7-dichlorotetramethylrhodamine (dTAMRA) and 4,7-dichloro-orthocarboxyrhodamine); ¶¶ 85 (fluorescein-type ring in which C9 is substituted with an orthocarboxy phenyl substituent); ¶ 88 (4,7-dichlorofluoresceins, 5-carboxyfluoresceine (5-FAM), 6-carboxyfluorescein (6-FAM), and 4,7-dichloro-ortho-carboxyfluorescein); ¶ 89 (cyanine, phthalocyanine, squaraine and bodipy dye); ¶ 153 (5-carboxysulfofluorescein); ¶ 156 (5-carboxy-

2',7'-dipyridyl-sulfofluorescein); and ¶ 163 (2',7'-dichloro-5-carboxy-4,7-dichlorofluorescein). Other examples of fluorescent moieties are incorporated by reference at ¶¶ 88 and 91.

Support for "an enzyme recognition moiety" can be found at ¶¶ 29-31, 61-67, and 118-123. Examples of enzyme recognition moieties can be found at ¶¶ 67 and 123, Schemes 1-7 and Tables 1 and 3.

Working examples showing the actual reduction to practice of various embodiments of the claimed substrate compounds can be found in Examples 1-11.

In view of the disclosure cited above, Applicant has described the claimed invention using words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Applicant also has provided several actual reductions to practice. Therefore, Applicant respectfully asserts that the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, that Applicant was in possession of the claimed invention. Applicant respectfully asserts that the specification fulfills the written description requirement and respectfully requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, ¶ 1, Enablement

Claims 1-27, 30, 33 and 34 stand rejected under 35 U.S.C. § 112, ¶ 1, as allegedly failing to comply with the enablement requirement. The Patent Office alleges that

> the specification is enabling for substrate compounds having different length alkylacyl groups prepared in phosphorylated and unphosphorylated form, represented by the following formula: X-Y(Dye)LRRASLG-NH_2, wherein X is a fatty acid acyl group of the form CH3(CH2)xC(=O)-, x is 0, 7, 10, or 14, Y is alpha-aminomethyl glycine, Dye is 4,7-dichlorofluoresceine dye attached to the 2-amine nitrogen atom of Y by a 5-carbonyl linkage to the pendant phenyl ring of the dye, wherein the enzyme recognition moiety consisting of amino acid sequence RRASL capable of being phosphorylated by Protein Kinase A, does not reasonably provide enablement for any substrate compound comprising any hydrophobic moiety capable of integrating the compound into a micelle, any fluorescent moiety, and any enzyme recognition moiety.

Office Action, p. 7. Applicant traverses the rejection.

The test for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the claimed invention is undue or unreasonable. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it

undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). Factors to be considered when determining whether any necessary experimentation is "undue" include but are not limited to: (i) the breadth of the claims; (ii) the nature of the invention; (iii) the state of the prior art; (iv) the level of one of ordinary skill in the art; (v) the level of predictability in the art; (vi) the amount of direction provided by the inventor; (vii) the existence of working examples; and (viii) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

M.P.E.P. § 2164.01(a) states:

> It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

Applicant respectfully asserts that all the various examples of the three types of moieties and working examples of the claimed compound demonstrate that the application is enabling for the full scope of the claims.

However, despite the factor analysis described above, according to M.P.E.P. § 2164.01(c):

> [w]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

Claim 1, the sole independent claim rejected for an alleged lack of enablement, is drawn to a substrate compound comprising: a hydrophobic moiety capable of integrating the compound into a micelle, a fluorescent moiety and an enzyme recognition moiety. Thus, the claimed compound is drawn to a composition that is not limited by a recited use of the compound. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).

Applicant respectfully asserts that multiple, enabled uses of the claimed compounds are provided throughout the specification. In addition, Examples 1-11 provide a plurality of reductions to practice within the scope of Claim 1. Furthermore, the Patent Office has acknowledged the enablement of a compound in phosphorylated and unphosphorylated form within the scope of the claimed invention. Thus, in view of the above standard that "if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention" Applicant respectfully asserts that the rejection is improper and respectfully requests that it be withdrawn. M.P.E.P. § 2164.01(c).

Rejection Under 35 U.S.C. §§ 102(a)(e)

Claims 1-6, 8, 20, 21, 23, 27, 33 and 34 stand rejected under 35 U.S.C. §§ 102(a)(e) as allegedly being anticipated by U.S. Patent No. 7,049,080 to Kramer *et al.* The Patent Office acknowledges that Kramer *et al.* do not disclose a "hydrophobic moiety capable of integrating the compound into a micelle" but asserts that the substrates disclosed by Kramer *et al.* include TAMRA, which inherently functions as the claimed hydrophobic moiety. Applicant traverses the rejection.

Applicant respectfully asserts that the claimed invention is drawn to three types of distinct moieties whereas Kramer *et al.*, as the Patent Office acknowledges, at least does not disclose the claimed hydrophobic moiety. Therefore, the rejection is improper under 35 U.S.C. § 102.

To support the rejection, the Patent Office sites the Sigma-Aldrich Catalog that states that 6-TAMRA is "soluble" in DMSO and methanol. Applicant respectfully asserts that the mere statement that 6-TAMRA is "soluble" in DMSO and methanol without more is insufficient to support the rejection under 35 U.S.C. § 102. The standard for anticipation under 35 U.S.C. § 102 is set forth in M.P.E.P. § 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In addition, "[t]he identical invention must be shown in as complete detail as is contained in the. . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully asserts that the Patent Office's position that TAMRA is "soluble" in DMSO and methanol and therefore inherently functions as the claimed hydrophobic moiety is unsubstantiated and the rejection should be withdrawn.

Double Patenting

Claims 1-27, 30, 33 and 34 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-12 and 15-33 of copending Application No. 11/035,682. Applicant respectfully requests this rejection be held in abeyance until there is an indication of otherwise patentable subject matter. Only at that time, will Applicant be able to assess the propriety of the rejection.

Conclusion

Claims 1-55 are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested.

No fees beyond a three-month extension of time are believed to be due in connection with this Amendment. However, the Director is authorized to charge any additional fees that may required, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 (**Order No. 375461-007US (355357)**).

Respectfully submitted,

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